OMB – OIRA – FDA Deeming Rule

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Agenda

Overview Nicopure Labs LLC

Deeming rule economic impact

Deeming rule leading to market concentration

Regulatory burden

Questions?

halo CIGS

EVO

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Nicopure Labs LLC

Since **2009**, Nicopure has provided the highest quality American-made eLiquid, electronic cigarettes, and vaping supplies available

Established in New Jersey and having moved to Florida in 2014, the company employed over 160 individuals in 2015

We have resellers in over 90 countries and already comply to a variety of applicable regulations in those countries

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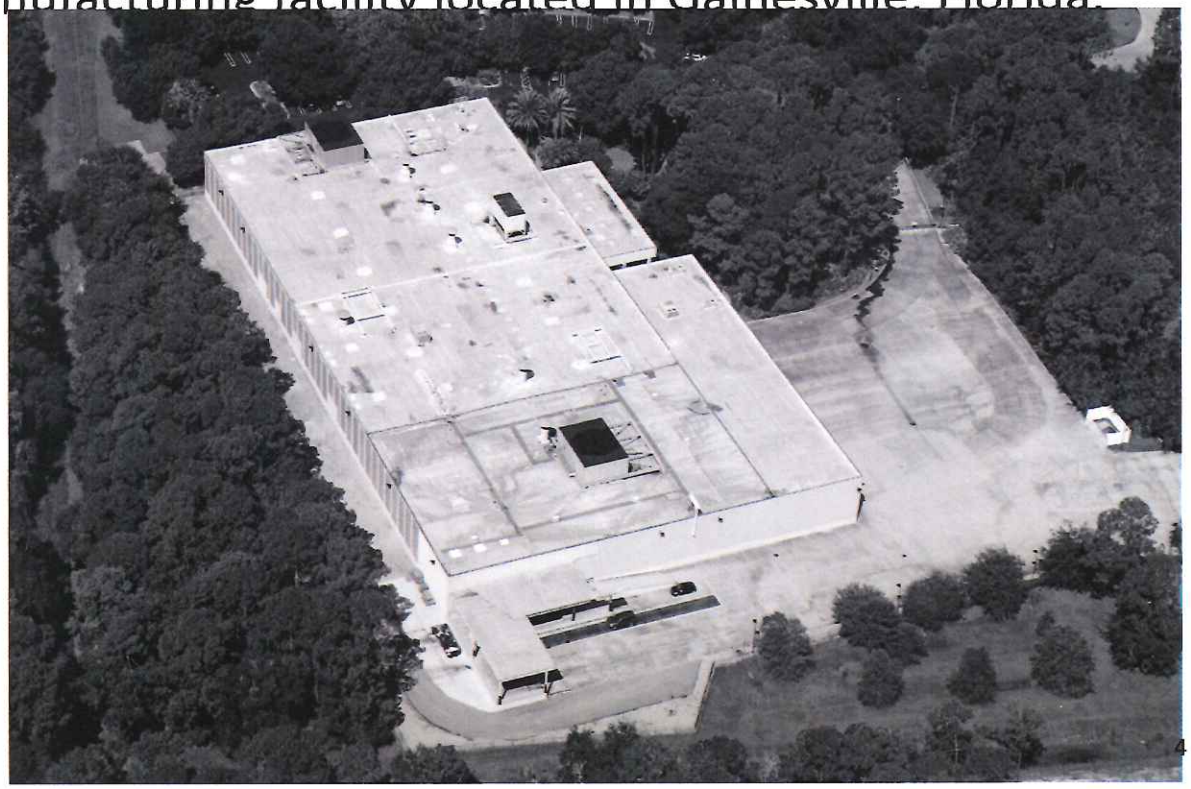
Nicopure Labs Manufacturing in Gainesville, Fl

Nicopure's commitment to quality is clearly evident in its 100,000 square foot, state-of-the-art manufacturing facility located in Gainesville, Florida.

- Consistent nicotine strength, flavor, performance
- strict adherence to quality guidelines
- drives product standards initiatives



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Market Leaders

Nicopure is an industry leader committed to responsible manufacturing practices and was among the first to include child-proof caps, best-by dating, and trackable lot numbers on all eLiquid bottles

From the Triton Tank Systems and G6 Cigarettes, to the 45+ flavors that make up its Halo and EVO line of eLiquids, Nicopure is proud to offer its customers products made with premium ingredients and the highest quality materials and components

We provide tamper evident banding, blue glass bottles to protect liquid from light and a three-month steeping process to ensure its customers are enjoying the freshest, best quality eLiquid

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Facts on economic impact of deeming rule

- Premarket review will immediately stifle innovation without acting on quality – bad actors will continue to be on the market for years before FDA takes the products off the market; those who won't file the necessary premarket documentation will paradoxically continue to operate while responsible players will go out of business due to the cost of compliance
- Current deeming rule precludes the substantial equivalence pathway, leaving only the PMTA pathway available for an industry made up of microenterprises with no resources to comply, very few (maybe six, including us) small enterprises that will try to comply and three major tobacco player (Altria, Reynolds and ITG Brands) that have resources to comply
- 99.9% of ecig products will be de facto banned
- Cost of creating a black market not taken into consideration

Cost of PMTA

- Recently approved Swedish Match PMTA included 150,000 pages of research, toxicology and ten years of epidemiological studies.
- No company, not even the tobacco companies making vaping products will be able to provide that kind of data
- A low estimate of the cost of a PMTA per SKU is 2-7 million, could be as high as $30,000,000 and 3,200 man/hours (depending on what FDA requests), plus ongoing costs for maintenance and post market surveillance. These costs are vastly above what FDA estimated in their burden ($330,000)
- FDA estimates only 1,600 vaping products on the market; Nicopure Labs LLC alone has over 100 SKUs and we believe the total number of SKUs is more in the hundreds of thousands
- FDA estimates 25 PMTA to be submitted for vaping products– therefore assumes 99.9% or products assumed banned?

What is within OMB/OIRA's purview?

- Executive Order 12866 requires agencies to conduct an analysis of the benefits and costs of rules and, to the extent permitted by law, directs that regulatory action shall only proceed on the basis of a reasoned determination that the benefits of a regulation justify the costs.

- Executive Order 12563 "Improving Regulation and Regulatory Review" provides, among other:

- "Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation"

- "It must identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends. It must take into account benefits and costs, both quantitative and qualitative"

- "Each agency shall identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public"

What can OMB/OIRA do?

- FDA has never considered flexible alternatives
- FDA has never even quantified the benefit to public health of regulating vaping products
- We know it is within OMB/OIRA's purview to require FDA to redraft rule that is mindful of economic impact and impact of black market and proportional to the cost to the economy, population and industry and we hope OMB/OIRA will use its